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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/724,778	11/28/2000	Jeffrey T. Finer	CYTOP009C1	9331

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EXAMINER

TRUONG, TAMTHOM NGO

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 07/03/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/724,778

Applicant(s)

FINER ET AL.

Examiner

Tamthom N. Truong

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, and 4-30 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1, and 4-30 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Applicant's preliminary amendment of 11-28-00 has been entered. Accordingly, claims 2, 3, and 31-59 are now cancelled; leaving claims 1, and 4-30 for consideration.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 1, 4-12, 15, 17, 20, 21, 23, 26, and 27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

a. Claims 1, 4-12, 15, 17, 20, 21, 23, 26, and 27 recite the broad recitation "substituted alkyl" or "substituted lower alkyl" (in the definition of R⁴), and the claims also recite "R₁₆-alkylene" which is the narrower statement of the range/limitation.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature

introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949).

b. Claim 12 lacks antecedent basis because it recites "butoxy" which is not a lower alkyl as recited in claim 11.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-10, 13, 14, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Padia** (US 5,756,502) over **Aono et. al.** (US 5,753,664).

Padia teaches several substituted quinazolinone compounds (e.g. see Examples 4 & 7) that are embraced by the first formula in claim 1 (i.e., 2-(R₃-C(O)-N(R₄)-C(R₂)(R₂'))-quinazolinone) having the following substituents:

- i. R₅ – R₈ – each represents hydrogen;
- ii. R₂, R₂', and R₄ – each represents hydrogen;
- iii. R₁ is substituted aryl (or substituted phenyl);

- iv. R_3 is heteroaryl or R_{15} -NH-;
- v. R_{15} is substituted aryl.

Padia uses his compounds as cholecystokinin (CCK) antagonists to reduce gastric acid secretion; whereas, the instant claims are directed to the treatment of cellular proliferative diseases. Such difference can be overcome by the teaching of Aono et. al. (US'664). Aono et. al. disclose a genus including substituted quinazolinone compounds, which can inhibit cell growth, and have excellent antitumor activity (e.g., see columns 2-16 of US'664). Thus, the teaching of Aono et. al. would have provided sufficient motivation for one skilled in the art to use some of the claimed quinazolinone compounds in the treatment of cellular proliferative diseases. Therefore, at the time of the invention, it would have been obvious to one skilled in the art to arrive at the claimed methods in view of the combined teachings above.

3. Claims 1, 23, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Pattanaik et. al.** (Ind. J. Chem., 12/1998, vol. 37B, pp. 1304-1306) in view of **Aono et. al.** (US'664).

On page 1305, Pattanaik et. al. disclose several compounds (i.e., 3 a – gg) in Table I, which are embraced by the last formula in claim 1 having the following substituents:

- vi. Two of $R_5 - R_8$ are halogens while the rest is hydrogen;
- vii. R_1 represents a substituted aryl;
- viii. R_2 and R_2' represent hydrogen;
- ix. R_4 is a substituted heteroaryl.

Although Pattanaik et. al. do not specifically associate their compounds with the activity of antitumor, they recognize that quinazolinones, in general, possess antitumor activity. Furthermore, as discussed above, the teaching of Aono et. al. would have motivated one skilled in the art to use compounds of Pattanaik et. al. in the treatment of cellular proliferative diseases. Thus, at the time of the invention, it would have been obvious to one skilled in the art to treat cellular proliferative diseases using some of the claimed compounds in view of the combined teachings above.

4. Claims 1, and 4-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over the "list of purchased compounds" (provided in co-pending application 9/699,047) in view of **Aono et. al.** (US'664). Applicants purchased several compounds claimed herein in October 2000. Thus, the compounds are not novel. Because Aono et. al. relate substituted quinazolinone compounds to the activity of antitumor, one skilled in the art would have been motivated to treat cellular proliferative diseases using the claimed compounds. Again, the claimed methods would have been obvious to one skilled in the art in view of Aono et. al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tamthom N. Truong whose telephone number is 703-305-4485. The examiner can normally be reached on M-F (9:00-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 703-308-4716. The fax phone numbers for the

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organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



Tamthom N. Truong
Examiner
Art Unit 1624

July 2, 2002